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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/644,380	08/23/2000	Floyd H. Chilton		1698

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EXAMINER	
JIANG, SHAOJIA A	
ART UNIT	**PAPER NUMBER**
1617	

DATE MAILED: 06/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/644,380	CHILTON, FLOYD H.	
	Examiner	Art Unit	
	Shaojia A. Jiang	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 February 2005 and 16 July 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *52-55* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *52-55* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 16, 2004 has been entered.

This Office Action is in response to Applicant's request for continued examination (RCE) filed July 16, 2004, and preliminary amendment, filed February 23, 2005 wherein claim 55 has been amended. Note that all claims 1-51 as originally filed have been cancelled previously.

Currently, claims 52-55 are pending in this application and examined on the merits herein.

This application is a CIP of PCT/US99/03120, WO 99/42101, which is a CIP of 09/028,256, now patented 6,107,334. However, the PCT, WO 99/42101 and the patent 6,107,334 upon, which priority is claimed fails to provide adequate support under 35 U.S.C. 112 for the instant new claims 52-55 of this application for RCE since both WO 99/42101 and 6,107,334 do not disclose the particular composition herein consisting essentially of specific ingredients in specific amounts.

Applicant's amendment filed February 23, 2005 with respect to the objection of claim 55 made under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the base claim 52 of record stated in the Office Action dated January 13, 2004 has been fully considered and found persuasive since the transitional phrase "comprising" has been removed from the claim. Therefore, this objection is withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 52-55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation "about" before the exact amount of each recited ingredient, e.g., "about 19.29 weight percent water" in claim 52 renders claims 52-55 indefinite since the term "about" is not clearly defined in the specification. More importantly, the precise amount, 19.29 g in total 100 g of the composition which is equal to precise 19.29 weight percent water, is given in the particular Example 11 at page 45 of the specification, but fails to teach about 19.29 weight percent water.

The court held that "subgenus range was not supported by generic disclosure and specific example within the subgenus range"; See, e.g., *In re Lukach*, 442 F.2d 967, 169 USPQ 795 (CCPA 1971); the court also held that "a subgenus is not necessarily

described by a genus encompassing it and a species upon which it reads" (see *In re Smith*, 458 F.2d 1389,1395, 173 USPQ 679, 683 (CCPA 1972). See also MPEP 2163.

The recitation, "marine oil" in the claim 52 render claims 52-55 herein indefinite. The recitation, "marine oil" is **not** clearly defined in the specification but merely gives one example, eicosapentaenic acid (EPA) is a marine oil.

Note that exemplification is not explicit definition. Hence, one of ordinary skill in the art could not ascertain and interpret the **metes and bounds** of the patent protection desired as to "marine oil" encompassed thereby.

Given the fact that not any "marine oil" is safe to be administered to a human or an animal.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 52-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over DeMichele et al. (5,223,285) in view of Igarashi et al. (EP 782827) and Kahn et al. (4,154,863) for the same reasons of record in the previous Office Action January 13, 2004.

DeMichele et al. discloses that fish oils (one of marine oils) are well known to contain eicosapentaenic acid (EPA) (see Fig-1 wherein the fish oil is eicosapentaenic acid) and borage oil is also well know to contain γ–linolenic acid (GLA). Fish oil (EPA) in 20% by weight and borage oil in 20% by weight are known to be used in a nutritional composition or a liquid nutritional product (see the particular formulation of Blend C at Table 2 at col.9 lines 32-65) according to DeMichele et al. Thus the sum of oils (marine oils and borage oil) is 40% by weight which would read on the instantly claimed *about* 35% of oils in claim 52, and the ratio of borage oil to fish oil is **1**. Note that the ratio of borage oil to fish oil, 57% to 43% in claim 53 herein is 1.32, *about 1*. The preferred nutritional compositions of DeMichele et al. comprise fish oil and borage oil, and vitamins such as vitamin C (also known as ascorbyl palmitate), water, sucrose, and stabilizer, and favoring agents, and their specific amounts (see col.15 line 65 to col.16 line 61, especially Table 7; Table 8 at col.17).

DeMichele et al. does not expressly disclose the employment of glycerin and particular minor ingredients in the particular composition herein. DeMichele et al. does not expressly disclose about 19.29 % wt of water, about 25 % wt of sucrose (sugar), about 15 % wt of flavoring and about 5 % wt of minor ingredients.

Igarashi et al. teaches that glycerin is a well known food-additive and used in food or nutritional composition such as the composition therein comprising omega-3 and omega-6 unsaturated fatty acids (see page 15 line 37 and page 10).

Kahn et al. teaches that the instant minor ingredients such as xanthan gum (a known stabilizer for food composition), colorant, sorbic acid, and palmitate, are known

to be used in a nutritional composition or food composition (see col.9 lines 21, 40, and 50, col.10 lines 15, 25-26, and 41-44, and particular compositions at col. 13 lines 50-67, col.15 lines 30-46, col.16 lines 20-34, col.17 lines 15-30, col.18 lines 11-24).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ glycerin and particular minor ingredients in a nutritional composition, and to optimize the amounts of the ingredients in a nutritional composition.

One having ordinary skill in the art at the time the invention was made would have been motivated to employ glycerin and particular minor ingredients in a nutritional composition herein since glycerin is known to be useful in a nutritional composition comprising fatty acids according to Igarashi et al.

Additionally, one having ordinary skill in the art at the time the invention was made would have been motivated to employ the instant minor ingredients such as xanthan gum, colorant, and sorbic acid, in a nutrition composition since these ingredients are well known, conventional, and art-recognized actives or additives to be used in a nutritional composition or food composition according to Kahn et al.

Further, one of ordinary skill in the art would have been motivated to optimize the effective amounts of active ingredients in a nutritional composition or a food composition because the optimization of known effective amounts of known ingredients to be administered is considered well within conventional skills in food and nutritional science or industry, involving merely routine skill in the art. It has been held that it is within the skill in the art to select optimal parameters, such as amounts of ingredients, in a

composition in order to achieve a beneficial effect. See *In re Boesch*, 205 USPQ 215 (CCPA 1980).

In view of the rejections to the pending claims set forth above, no claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (571)272-0627. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on (571)272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

S. Anna Jiang, Ph.D.
Primary Examiner
Art Unit 1617
May 25, 2005